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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/803,773	03/12/2001	Judah Z. Weinberger	56330-A/JPW/PJP	8786

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Cooper & Dunham LLP
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EXAMINER

MARMOR II, CHARLES ALAN

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 11/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Talk

Office Action Summary	Application No.	Applicant(s)	
	09/803,773	WEINBERGER, JUDAH Z.	
	Examiner	Art Unit	
	Charles A. Marmor, II	3736	

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-11 and 22-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-11 and 22-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on September 15, 2005 and July 21, 2004 has been entered.

The Examiner acknowledges the amendments to claims 1 and 8. The Examiner further notes that claim 22 has been identified as "Previously Presented" although the claim includes markings indicating amendments have been made to that claim. In order to expedite prosecution of the instant application, the Examiner will consider the status of claim 22 to be "Currently Amended" and acknowledge the amendments made therein. Claims 1-4, 6-11 and 22-29 are pending.

Claim Objections

2. Claim 4 is objected to because of the following informalities: at line 4, a comma should be inserted following "process". Appropriate correction is required.
3. Claim 22 is objected to because of the following informalities:
 - a. At line 9, a comma should be inserted following "balloon".

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- b. At line 10, “catheter” apparently should be deleted.
- c. At lines 11-12, the limitation “and which includes radioactive material” is redundant and should be deleted.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-4, 6-11 and 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1, 8 and 22 have been amended to recite that the tube segment has radioactive material “substantially uniformly disbursed throughout its structure.” The original disclosure fails to disclose such a feature. Applicant alleges that support for the amendment may be found at least in Figure 3. The Examiner respectfully disagrees. Figure 3 illustrates a radioactive tube segment located outside a balloon of a balloon catheter according to a second embodiment of the invention (see page 7, lines 10-12 and page 13, lines 4-7). The tube segment is hatched in the drawing; however, nothing in the original disclosure indicates that this hatching implies that radioactive material is uniformly disbursed throughout the structure of the tube segment. The only time the hatching is mentioned in the original disclosure appears to be with

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respect to Figure 4, where the tube segment having radioactive material is hatched in order to distinguish from a non-radioactive remainder of the tube that is unhatched (see page 13, lines 26-30). The original specification discloses at page 8, lines 13-17; page 8, lines 28-31; page 10, lines 23-29; and page 13, lines 23-30 various configurations of the radioactive material with respect to the tube segment; however, none of these citations nor any other portion of the original disclosure describe in full, clear, concise and exact terms that the radioactive material is uniformly disbursed throughout the structure of the tube segment.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. At lines 9-10 of claim 1, the limitation “and being made of expandable and collapsible material” renders the claim indefinite because it is unclear whether the limitation is directed to the tube segment, the catheter, or the balloon.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for

patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1, 3, 7, 8, 10 and 22 rejected under 35 U.S.C. 102(e) as being anticipated by Klein ('284). Klein teaches an apparatus for radiation treatment of an internal body lumen. The apparatus includes a balloon catheter **34** having an inflatable balloon **32** and a tube segment. The tube segment is defined as the radiation-emitting terminal portion of catheter **10**, which is consistent with the disclosure of the instant application at page 9, lines 1-4. The entire tube segment is adapted to be longitudinally slid over, carried by and cover the balloon. The radiation-emitting tube segment is substantially the same length as the balloon (see at least Figures 5-8). The tube segment includes a radioactive material **30,302** that is mixed with a non-radioactive material **38** (col. 24, lines 65-67). The radioactive material is uniformly disbursed throughout the structure of the tube segment formed by the radiation-emitting terminal portion of catheter **10**, and particularly when considered longitudinally. The tube segment can be an expandable and collapsible material, such that the tube segment is expandable in a range of sizes and the entire shape of the tube segment is determined by the shape of the balloon as the balloon inflates to expand the segment and deflates to collapse the segment. Embodiments of the tube segment are formed of an elastomeric material that covers the balloon substantially entirely during inflation (col. 12, lines 35-39 and Figs. 5-6). The outer surface of the tube segment is exposed to come into direct contact with the luminal structure. In operation, the balloon catheter **34** is inserted into the body lumen; the radioactive tube segment at the terminal portion of catheter **10** is longitudinally slid over the balloon catheter **34** such that the tube segment including the radioactive material **30,302** is disposed over the balloon **32**; the balloon **32** is

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inflated with fluid to expand the tube segment and administer a radiation dose to the luminal structure; the balloon 32 is deflated and the tube segment collapsed; and the balloon catheter 34 and tube segment are removed from the luminal structure.

10. The indicated allowability of claims 25-29 is withdrawn in view of the newly discovered reference(s) to Roubin et al. ('257). Rejections based on the newly cited reference(s) follow.

11. Claims 25-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Roubin et al. ('257). Roubin et al. teach a minimally invasive medical device for providing radiation treatment in the vicinity of a luminal structure (see Figure 5). The tube segment 59 includes radioactive material 63 for producing radiation for treating a disease process. The tube segment has varying concentrations of radioactive material for producing a radiation dose that varies at least axially and longitudinally along the tube segment. The tube segment 59 has substantially equal wall thickness along its longitudinal length (see Figure 5).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 2 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein ('284) in view of Hess ('168). Klein teaches all of the limitations of the claims except that the

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radioactive material is in the form of a coating on the tube segment. It is well known in the art that a non-radioactive material can be provided with radioactive characteristics by coating the non-radioactive material with a radioactive material. Hess teaches a stent 74 which is coated with a radioactive material in order to assist in preventing restenosis of an artery. It would have been an obvious engineering design choice to one skilled in the art at the time the invention was made to make a radioactive tubular segment similar that of Klein by coating a tubular segment with a radioactive material in view of the teachings of Hess in order to produce a tube that is radioactive at its distal end.

14. Claims 4 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein ('284) in view of Lewis et al. ('552). Klein teaches all of the limitations of the claims except that the tube segment includes a non-radioactive material into which is absorbed radioactive material. Lewis et al. teach that it is known in the art to make intra-luminal radiation devices of a non-radioactive material into which is absorbed radioactive material. It would have been an obvious engineering design choice to one skilled in the art at the time the invention was made to make a radioactive tubular segment similar that of Klein by absorbing radioactive material into a non-radioactive material in view of the teachings of Lewis et al. in order to produce a tube that is radioactive at its distal end.

15. Claims 6, 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein ('284) in view of Fischell et al. ('282). Klein teaches all of the limitations of the claims except that the tube segment is adhesively attached to the balloon and that the balloon is inflated with a

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gas. Fischell et al. teach a catheter having an expandable radioactive source. The catheter includes a balloon **14** with an expandable, elastic radioactive tube segment **16** adhesively attached to the balloon **14** by an outer balloon **15** which is heat sealed (shrunk) to the inner balloon (col. 5, lines 2-6). The balloon **14** is inflated with a carbon dioxide gas to bring the tube segment into proximity to a luminal structure (col. 6, lines 51-53). It would have been obvious to one having ordinary skill in the art that since the radioactive source **16** is expandable and elastic, the dosage per surface area of the source would inherently be different in an inflated state than that of the unexpanded state. It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to adhesively attach the tube segment to the balloon of a radiation treatment device similar to that of Klein in view of the teachings of Fischell et al. in order to ensure proper positioning of the expandable radioactive tube segment with respect to the balloon. It further would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to use a carbon dioxide gas as an inflation medium in view of the teachings of Fischell et al. in order to inflate the balloon catheter of a device similar to that of Klein as an obvious engineering design choice, merely substituting one known inflation medium for another that is capable of performing the same function.

16. Claims 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roubin et al. ('257) in view of Pflueger ('038). Roubin et al, as discussed above, teach all of the limitations of the claims except that a balloon catheter having a shaft and an inflatable balloon is provided and that the tube segment is adapted to be carried by and cover the balloon. Roubin et al. instead teach that a guidewire **65** is positioned in the lumen **62** of the tube segment **59**.

Pflueger teaches that a balloon catheter 12 including a shaft and an inflatable balloon 30 may be inserted maneuvered through the lumen of a tubular catheter in order to secure the positioning of the catheter within the body. It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to use a balloon catheter similar to that of Pflueger as the guidewire in a tube segment similar to that of Roubin et al. in order to anchor the tube segment at a desired treatment position in a body lumen.

Response to Arguments

17. Applicant's arguments filed July 21, 2004 have been fully considered but they are not persuasive.

Applicant contends that Klein fails to teach or suggest a tube segment that is substantially the same length as the balloon and has radioactive material substantially uniformly throughout its structure. Applicant argues that when the tube segment is considered to be element 10, element 10 is a tube substantially longer than the length of the inflating balloon segment, as illustrated in Figures 5 and 6. Applicant finally asserts that the radioactive elements 30 of Klein are arranged only intermittently around the circumference, as illustrated in Figures 11 and 12.

The Examiner respectfully submits that the tube segment of Klein may be considered any segment of the tube 10 of Klein. The tube segment formed by the radiation-emitting portion adjacent the terminal end of the tube 10 of Klein reads on all of the limitations of the claims. That is, such a tube segment includes radioactive material that may be considered to be uniformly disbursed throughout the structure of the tube segment; is adapted to be longitudinally slid over and carried by a balloon; is expandable and collapsible; is substantially the same length

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as the balloon; substantially covers the entire length of the balloon during inflation; has a shape determined by the shape of the balloon; and has an outer surface exposed to come into direct contact with the luminal structure. Considering the radioactive material-bearing tube segment to be a portion of a longer tube is consistent with the specification of the instant application at page 9, lines 1-4 and page 13, lines 23-30. Moreover, such an interpretation of tube segment is consistent with the embodiment of the invention where the tube segment is longitudinally slideable over the balloon as required by each of independent claims 1, 8 and 22. The Examiner notes that in the embodiments of the instant invention where the entire tube including the tube segment is the same length as the balloon, such as that illustrated in Figure 3, the specification only discloses such a tube segment to be attached to the balloon by heat sealing or adhesive in which case the tube segment would no longer be longitudinally slideable over the balloon after assembly.

Regarding Applicant's argument that the radioactive elements 30 of Klein are arranged only intermittently around the circumference as illustrated in Figures 11 and 12, the Examiner does not disagree with this statement. However, the Examiner respectfully submits that the radioactive material of Klein may be considered to be substantially uniformly disbursed throughout the structure of the tube segment, as required by the language of the claim. The claims do not require that the radioactive material be uniformly disbursed about the entire circumference of the tube segment. The radioactive material of Klein may be considered to be uniformly disbursed throughout the structure of the tube segment in that it is disbursed in a uniform and symmetrical fashion throughout the structure that forms the tube segment.

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Moreover, the radioactive material of Klein may be considered to be uniformly disbursed throughout the longitudinal structure forming the tube segment.

In view of the foregoing, the rejections citing Klein ('284) are maintained.

Conclusion

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (571) 272-4730. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles A. Marmor, II
Primary Examiner
Art Unit 3736